OPERATOR AND MAINTENANCE MANUAL

DELFI PTS ii PORTABLE TOURNIQUET SYSTEM

REF 9-2200-001X

U.S. PATENTS 6,213,939; 5,931,853; 5,649,954 PAT. PEND. and FOREIGN PATENTS

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LIMITED TWO YEAR WARRANTY (North America. only)

SCOPE OF WARRANTY

Delfi Medical Innovations Inc. ('Delfi') warrants the PTS ii Portable Tourniquet System ('product') for two years from date of purchase. During the warranty period, Delfi will repair or replace, at its option, any product which is defective in materials or workmanship or which fails to meet the published specification for that model. This Limited Warranty is made only to the original purchaser of the product and is non-transferable. The remedies described in the Limited Warranty are the exclusive remedies for breach of warranty. THIS WARRANTY SHALL NOT APPLY TO ANY PRODUCT WHICH HAS BEEN ALTERED, MODIFIED, DISASSEMBLED OR SERVICED BY ANYONE OTHER THAN DELFI STAFF IN ANY WAY, OR WHICH HAS BEEN SUBJECTED TO MISUSE OR ABUSE.

DISCLAIMER OF IMPLIED WARRANTIES

The foregoing Express Limited Warranty is given in lieu of any and all other express or implied warranties. DELFI MAKES NO OTHER WARRANTIES INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

LIMITATION OF REMEDIES

In no case shall Delfi Medical Innovations Inc. be liable for any special incidental or consequential damages whether based on breach of warranty or other legal theory. Some states do not allow limitations on warranties or on remedies for breach in certain transactions. In such states, the limits in this paragraph and the preceding paragraph do not apply.

WARRANTY CLAIMS

In the event of a warranty claim within the warranty period please take the following steps:
1. Notify Customer Service Department, Delfi Medical Innovations Inc. at 800-933-3022. Please provide details about the nature of the problem and include the product serial number. Upon receipt of this information, Delfi will provide a date for service or a return shipping authorization.
2. Upon receipt of the shipping authorization, forward the equipment, freight prepaid, to the location specified in the shipping authorization.

Your compliance with these steps will help assure that you receive prompt warranty service for your product.

WARRANTY (OUTSIDE North America)

Please contact Delfi for warranty information.

Unit Serial Number _____

AC Power Supply Serial Number _____

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FIGURES and TABLES:

GENERAL INFORMATION

SECTION 1.0
DELFI PTS ii TOURNIQUET SYSTEM

1.1 SPECIFICATIONS

REF 9-2200-001B – Blue Front Panel
REF 9-2200-001R – Red Front Panel

AC Power Adaptor:
Use only supplied AC adapter / power cord assembly Delfi
REF 7-2200-020 (Single Output) or
REF 7-2200-021 (Dual Output)

Mains Line Voltage Range:
100-240 ~ (AC), 50/60 Hz. Auto switching

Line current:
175 mA RMS @ 120V ~ (AC) Typical
(REF 7-2200-020 Single Output)
300 mA RMS @ 120V ~ (AC) Typical
(REF 7-2200-021 Dual Output)

Input Power:
100 watts maximum REF 7-2200-020
100 watts maximum REF 7-2200-021

AC Power plug: (North America)
Hospital grade, 3 prong straight blade, 15 amp

Battery Type:
12V nickel-metal-hydride (NiMh) internally protected pack, 2200 milliamp hours
Use only Delfi REF 7-2200-007 battery pack

Battery Recharge Time:
10.0 hours (typical)

Cuff Pressure Range:
50 - 600 mmHg, 5 mmHg increments

Pressure Accuracy:
+/- 2 mmHg

Pressure Regulation:
+/- 6 mmHg of set point (10-second average under non transient conditions without external leaks)

Time Alarm Set Point Range:
0-240 minutes, 5 minute increments

Timer Accuracy:
0.1% of elapsed time

Inflation Rate:
34 inch cuff applied to a 30 inch thigh inflates to 350 mmHg in less than 5 seconds

Deflation Rate:
34 inch cuff applied to a 30 inch thigh deflates to less than 10 mmHg in less than 10 seconds

Internal Diagnostics:
Program, memory, watchdog timer, transducer calibration, improper valve actuation.

Display:
Color 240x320 LCD Backlit

Indicators:
AC Indicator Light – Green
Alarm Indicator Light - Red

Controls:
Seven buttons located on the front panel

Printer Interface:
RS232 9600 Baud

Size:

Height:	180 mm	(7.0 inches)
Width:	120 mm	(4.7 inches)
Depth:	110 mm	(4.3 inches)
Weight	1.08 kg	(38.0 oz)

Environmental:

Operating temperature: 10 to 40 °C (15 to 105 °F)

Storage temperature: -20 to 40 °C (-4 to 105 °F)

Humidity: Max 80 % non-condensing

This device is not suitable for use in the presence of flammable anesthetic or gases

Electromagentic Compatability (EMC):
This medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration - electromagnetic emissions		
The PTS ii tourniquet system is intended for use in the electromagnetic environment specified below. The user of the PTS ii tourniquet system should assure that is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment guidance
RF emissions CISPIR 11	Group 1	The PTS ii tourniquet system uses RF energy only for its internal function. Therefore only its RF emissions are very low and not likely to cause interference in nearby electronic equipment.
RF emissions CISPIR 11	Class A	The PTS ii system is suitable for use in all establishments other than those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Additional EMC compatibility information available at www.delfimedical.com

NOTE: Use this tourniquet system according to the policies in your practice setting. The following information on intended use, precautions, contraindications, and adverse effects are offered as a guide to assist in this process.

1.2 INTENDED USE

The Delfi PTS ii Portable Tourniquet System is intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremity during surgical procedures on that extremity. Tourniquets are generally used for operations lasting less than 90 minutes. Tourniquets have been found useful in producing a bloodless operation field in surgical procedures involving the extremities including:

- Reduction of certain fractures
- Kirschner wire removal
- Tumor and cyst excisions
- Knee joint replacements
- Arthroscopy of certain joints
- Replacement of finger joints
- Bone grafts
- Amputations
- Subcutaneous fasciotomy
- Nerve injuries
- Tendon repair
- Total wrist joint replacement

WARNING: Do not use tourniquet cuffs to control the distal flow of CO_2 or any other gases used as a distention media. Tourniquet cuffs have not been evaluated for safety or effectiveness in controlling gas flow beyond the surgical site during arthroscopic insufflation procedures. Possible effects of using a tourniquet cuff in this manner include serious subcutaneous emphysema proximal to the cuff.

1.3 CONTRAINDICATIONS

Refer to the medical literature for possible contra-indications to tourniquet use. A partial list is provided below, however in every case the final decision to use a tourniquet rests with the attending physician.

- Open fractures of the leg
- Post-traumatic lengthy hand reconstruction
- Severe crushing injuries
- Diabetes mellitus
- Severe hypertension
- Elbow surgery (where there is concomitant excess swelling)
- Skin grafts in which all bleeding points must be readily distinguished
- Compromised vascular circulation, e.g., peripheral artery disease
- Sickle cell disease or trait (relative contraindication, see PRECAUTIONS IN USE).
- Secondary or delayed procedures after immobilization.

1.4 PRECAUTIONS IN USE

- The tourniquet system must be kept well calibrated and in operable condition. Accessories should be checked regularly for leaks and other defects.
- The tourniquet cuff must never be punctured; therefore towel clips used near the system must be handled with special care.
- Cuffs with inner rubber bladders must be completely enclosed by the outer envelope to preclude ballooning and possible rupture of the bladder. Cleaning and assembly instructions of the cuff manufacturer should be followed carefully.
- Do not use an elastic bandage for exsanguination in cases where this will cause bacteria, exotoxins, or malignant cells to spread to the general circulation, or where it could dislodge thromboemboli that may have formed in the vessels.
- The tourniquet cuff must be applied in the proper location on the limb. Tourniquet pressure and the time the tourniquet is inflated on the limb should both be minimized. There is additional potential risk to superficial nerves in unprotected areas; never apply a tourniquet over an area where major nerves may be directly compressed against bone (eg. peroneal nerve near the proximal head of the fibula). Never apply a tourniquet over the joints of the limb. Do not readjust an already inflated cuff by rotating it because this produces shearing forces which may damage the underlying tissue. Prolonged ischemia may lead to temporary or permanent damage to tissues, blood vessels, and nerves.
- Prolonged tourniquet time can also produce changes in the coagulability of the blood with increased clotting time. Always minimize tourniquet time
- Tourniquet paralysis may result from excessive pressure. Insufficient pressure may result in passive congestion of the limb with possible irreversible functional loss. Always use the minimum effective tourniquet pressure, as described in the medical literature.
- Inflation should be done rapidly to occlude arteries and veins as near simultaneously as possible.
- Careful and complete exsanguination reportedly prolongs pain-free tourniquet time and improves the quality of Intravenous Regional Anesthesia (Bier Block anesthesia). In the presence of infection and painful fractures, after the patient has been in a cast, and in amputations due to malignant tumors, exsan-

guination before tourniquet application may be done without the use of an elastic bandage by elevating the limb for 3 to 5 minutes.

- In case of failure, the tourniquet cuff must be fully deflated and the limb exsanguinated again before reinflation. Reinflation over blood-filled vasculature may lead to intravascular thrombosis.
- Tourniquet users must be familiar with the inflation / deflation sequence when using two tourniquet cuffs and two PTS ii units together for IVRA (Bier Block anesthesia), so that the wrong tourniquet will not be released accidentally.
- Test for hemoglobin type and level before using a tourniquet on patients with sickle-cell anemia. When the tourniquet is used for these patients, the limb should be carefully exsanguinated and the PO2 and pH should be closely monitored.
- Select the proper cuff size to allow for the overlap recommended by the cuff manufacturer. Too much or too little overlap may cause cuff rolling and telescoping, unexpected release of the cuff from the limb, inability to maintain a bloodless field at normal pressures, and/or undesired pressure distribution on the limb.
- The skin under the tourniquet cuff must be protected from mechanical injury by smooth, wrinkle-free application of the cuff. If the tourniquet cuff is applied over any material that may shed loose fibers (such as Webril) the fibers may become embedded in the contact closures and reduce their effectiveness. Follow the cuff manufacturer's recommendations for limb protection material under the cuff. In general, a limb protection sleeve designed specifically for the cuff provides the best protection.
- If skin preparations are used preoperatively, they should not be allowed to flow nor collect under the cuff where they may cause chemical burns.
- Whenever the tourniquet cuff pressure is released, the wound should be protected from blood surging back by applying pressure dressings and, if necessary, elevating the limb. Transient pain upon tourniquet pressure release can be lessened by elevation of the limb. If full color does not return within 3 to 4 minutes after release, the limb should be placed in a position slightly below body level.
- The deflated cuff and any underlying limb protection material should be completely removed as soon as tourniquet pressure is released. After the cuff has been fully deflated and removed from the patient, the unit can be set to STANDBY. Even the slightest impedance of venous return may lead to congestion and pooling of blood in the operative field.
- Whenever IVRA (Bier Block anesthesia) is used, it is recommended that the tourniquet remain inflated for at least 20 minutes from the time of injection.

1.5 ADVERSE EFFECTS

A dull aching pain (tourniquet pain) may develop throughout the limb following use. Stiffness, weakness, reactive hyperemia, & skin discolouration may also occur to some degree in all patients after tourniquet use.

Pathophysiologic changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissues occur and become significant after about 1 1/2 hours of tourniquet use.

Symptoms of tourniquet paralysis are motor paralysis and loss of sense of touch, pressure, and proprioceptive responses.

Intraoperative bleeding may be caused by:

1. The slight impeding effect exerted by an unpressurized cuff (and its limb protection material or padding, if used), which prevents venous return at the beginning of the operation,
2. Blood remaining in the limb because of insufficient exsanguination,
3. Inadequate tourniquet pressure, or slow inflation and deflation, all if which allow arterial blood to enter while preventing venous return,
4. Blood entering through the nutrient vessels of the long bones, such as the femur or humerus.

INSTALLATION AND OPERATING INSTRUCTIONS

SECTION 2.0

DELFI PTS ii TOURNIQUET SYSTEM

2.1 INITIAL INSPECTION

Unpack the PTS ii upon receipt and inspect the unit for any obvious damage that may have occurred during shipment. We recommend that this inspection be performed by a qualified biomedical engineer or other person thoroughly familiar with electronic medical devices. If the unit is damaged, notify the carrier and Delfi immediately. If the initial inspection results are satisfactory, a functional and calibration check should be performed after an 10 hour charge. The attention label covering the pressure/time display window button may be removed and discarded after the initial 10 hour charge.

2.2 CONTROLS, INDICATORS, LCD DISPLAY, AND CONNECTORS

Refer to Figure 2.1 for the locations of the unit's controls, indicators, displays and connectors described below:

1. ON/STANDBY Button

Turns the unit on or sets the unit to standby. In standby mode (powered off), the power to all instrument functions (i.e. inflation, deflation, etc.) is off, but power continues to supply the battery charging circuitry whenever AC power is present. This button will not set the unit to standby when there is pressure in the cuff. Ensure the cuff is fully deflated, and the cuff and limb protection material have been removed from the patient prior to setting the unit to standby.

2. INFLATE Button

Inflates the cuff to the pressure set point and starts the elapsed time monitor. Momentarily depressing the 'INFLATE' button immediately begins rapid inflation of the cuff.

3. DEFLATE Button

Deflates the cuff and stops the elapsed time monitor. To prevent accidental deflation of the cuff, the 'DEFLATE' button has a delay and must be pressed and held for approximately 2 seconds before the unit will deflate the cuff. A short tone is sounded after the 2 second delay to indicate that deflation has started and the user may then release the 'DEFLATE' button. If the user momentarily presses then releases the 'DEFLATE' button, nothing happens. If the user releases the 'DEFLATE' button any time after deflation has begun, the cuff continues to deflate to zero pressure.

4. MULTIFUNCTION Buttons

The four buttons located underneath the display screen. The action associated with a button is clearly indicated by the icon displayed above the button. More details regarding the functions of each of these buttons is provided in the sections below.

Icon	Function
	Set pressure set point
	Set time limit set point
	Print event history
	System settings and special functions
	Go back to the previous screen
	Increment
	Decrement
	Acknowledge
	Alarm Silence Silence the audio alarm for 30 seconds
	Reset elapsed inflation time to zero
	Leak test
	Stop a cuff leak test

5. Color Display

The color LCD display of the PTS ii conveys various operating information to the user. During normal operation with no buttons being pressed, the display shows the current sensed cuff pressure in mmHg and the number of minutes the cuff has been inflated (tourniquet time). Alarm conditions and battery level indicator may also be displayed depending on the operating condition of the system.

6. AC Power Indicator Light

The green AC power indicator light is illuminated at all times when AC power is plugged in to the PTS ii, both in ON and STANDBY modes. Note that the AC power indicator light remains off at all times when there is no AC power connected to the PTS ii.

7. Alarm Indicator Light

The red alarm indicator light is illuminated when any alarm condition exists. The alarm indicator will remain illuminated until the alarm condition is corrected, as long as sufficient power is available.

8. Battery Indicator Symbol

The battery indicator symbol in the center of the color LCD display is visible when the PTS ii is on and operating on battery power (AC power not connected). The battery indicator symbol is composed of a colored bar and a battery icon. The length and color of the bar indicate the charge level of the battery. When the colored bar completely fills the battery icon, the battery has a full charge. Reducing length of the bar and the change in color from green to red progressively indicate decreasing battery capacity and the need for recharging. The battery indicator disappears when AC power is connected to the PTS ii.

9. Hose Connector

The hose assembly (see below) leading to the tourniquet cuff plugs in to the PTS ii unit at the hose connector. The hose connector is a positive locking type that makes an audible 'click' when properly connected.

10. Hose Assembly

One hose assembly is supplied with each PTS ii unit. The male positive locking connector plugs in to the hose connector on the PTS ii unit (see above). The female end attaches to the tourniquet cuff. The PTS ii is designed, tested, and recommended for use with Delfi and other single port cuffs having Positive Locking Connectors only. Use the supplied hose assembly only. An adapter is provided with the PTS ii unit for connection to calibration equipment.

To engage Positive Locking Connectors fully depress and then release the metal locking button. Carefully slide the connectors together. An audible 'click' can be heard when properly connected and locked. To disengage fully depress and hold the metal locking button. Carefully separate the connector while holding the metal locking button. Excessive force is not required. To prevent O-ring damage the metal locking button must always be in the open position before connectors are engaged or disengaged.

11. Power Receptacle

The power receptacle is located on the left of the battery from a rear view of the PTS ii unit. The PTS ii is designed for use with the supplied AC power supply (see below) only; do not use any other type of connection to AC power .

12. AC Power Supply

An AC power supply adapter is supplied with every PTS ii unit. It is a sealed unit designed specifically for the PTS ii. Contact Delfi if your power supply needs service or replacement. Plug the connector on the AC power supply cord into the AC power receptacle on the PTS ii unit (see above), and plug the AC power cord into a power outlet (see below) whenever using the unit where AC power is easily accessible.

13. AC Power Cord

An AC power cord with a hospital grade plug is supplied with every PTS ii unit. Plug the socket end of the cord into the AC power supply and the plug end into an AC power outlet.

14. Tourniquet Information Port

Located on the right of the battery compartment from a rear view of the PTS ii unit the tourniquet information port connects to an external printer (Delfi REF 9-2200-350) or to an external information system.

15. Pole mount bracket attachment points

Used to secure the PTS ii instrument to a pole mounting bracket. Use only Delfi REF 7-2200-008 bracket for single systems or Delfi REF 7-2200-009 bracket for twin systems. See Figures 2.2 and 2.3

Note: To ensure stability do not mount above a height of 5.0' (1.5m) on mobile IV poles.

Figure 2.1: PTS ii Controls, Indicators, Displays, and Connectors

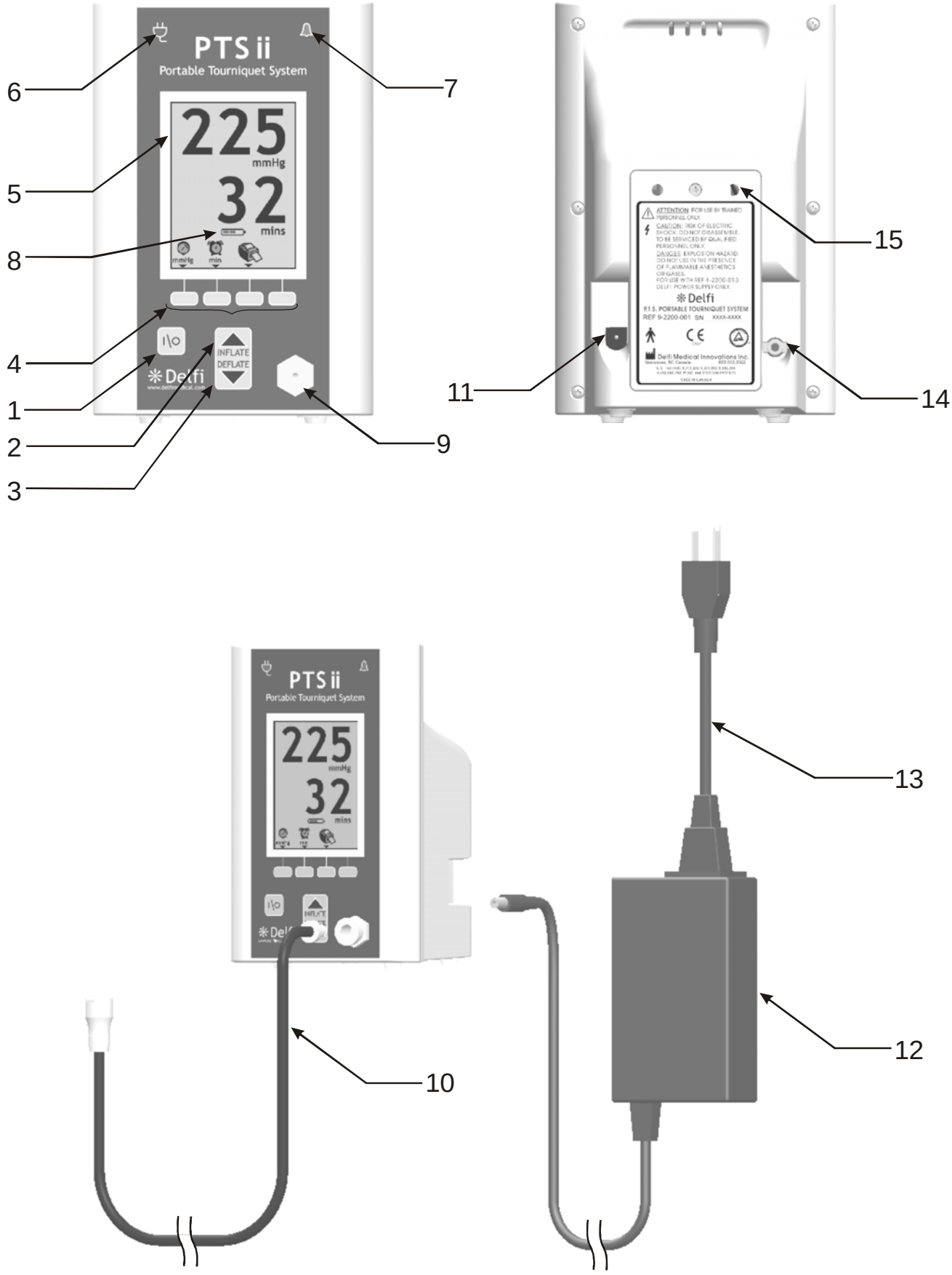
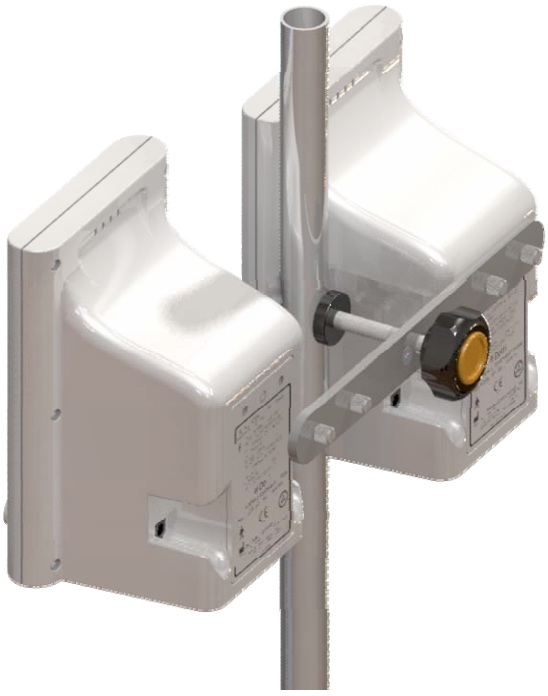


Figure 2.2: PTS ii Single system mounting bracket (7-2200-008)

Figure 2.3: PTS ii Twin system mounting bracket (7-2200-009)



2.3 INITIAL SETUP

During shipping and storage, the unit's battery could become weak. Prior to initial use, the unit must be plugged into AC power using the AC power supply and cord assembly until the battery is fully charged. This initial charge should take no more than 10 hours. The battery must be fully charged before any initial use, including any calibration checking procedures, initial checks, or tests performed by biomedical engineering at your facility.

WARNING: Use only a Delfi REF 7-2200-020 or 7-2200-021 AC power supply and cord assembly supplied with your PTS ii. Do not use any other AC power supply or cord. Use of an improper power supply may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the PTS ii unit.

CAUTION: Avoid exposing the AC power supply to liquids. Do not immerse in fluid. Do not allow the AC power supply to lie on the floor where pooling of liquids may occur. Clean by damp cloth (alcohol or mild detergent wipe) only. The AC power supply is resistant to occasional splashing or dripping of fluids, but is not fluid-tight. If immersed in or exposed to excessive amounts of liquids, the AC power supply may fail and may pose an electrical shock hazard.

WARNING: Use battery packs supplied by Delfi only. Do not use any other any other battery pack. Use of an improper battery pack may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the PTS ii unit.

2.4 FUNCTIONAL AND CALIBRATION CHECK

Each PTS ii unit is fully tested before shipping. However, the following functional and calibration checks should be performed by the user before the first clinical use of the PTS ii unit to ensure that it has not been damaged in shipping. After charging the battery as described above, the unit shall produce the results explained in the following steps exactly as indicated. Failure to do so indicates that a problem may exist and the device is not to be used until necessary repair or calibration has been made.

2.4.1 AC POWER CONNECTION AND INDICATOR

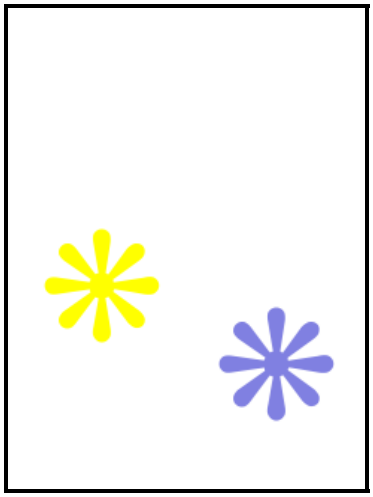
Connect the power supply to the PTS ii system then connect the AC power plug to a properly polarized and grounded power source with voltage and frequency characteristics compatible with the specifications listed in Section 1.1. Observe that the green AC power indicator light turns on.

2.4.2 POWER-UP SEQUENCE AND SELF-TESTS

Power up the unit by pressing the 'ON/STANDBY' button and observe the following (the PTS ii may be plugged in to AC power or not for the remaining tests):

a) The backlight of the LCD display lights up, a welcome screen (Figure 2.2) is displayed, and a welcome audio tone is sounded. Note that if AC power is not connected, the green AC power indicator light does not come on at any time, and if AC power is connected it remains on constantly.

Figure 2.2
Welcome Screen



b) Self-test screen is displayed (Figure 2.3). During this time, the unit is self-testing specific system hardware and software

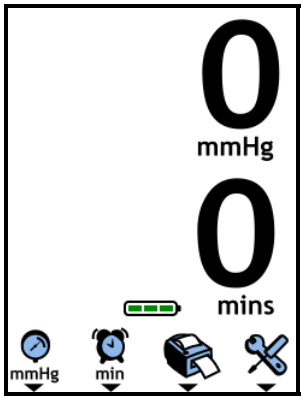
Figure 2.3
Self Test Screen

c) Calibration-check is displayed (Figure 2.4). During this time, the unit is checking its calibration at zero pressure.

Figure 2.4
Calibration Check

d) Main screen is displayed (Figure 2.5). The cuff pressure and tourniquet time are shown. The battery status indicator will not be shown if the unit is powered from an AC supply.

Figure 2.5
Main Screen



2.4.3 CALIBRATION CHECK

NOTE: Every PTS ii unit is calibrated at the factory before shipping. The unit also self-tests specific calibration parameters upon power-up. Should a potential out of calibration condition be detected, the unit will display error messages (see Table 2.1). However even though the unit performs a self-test of calibration at every power-up, the following quantitative check is recommended prior to initial use, and at regular intervals according to the policies in your practice setting.

a) Connect the PTS ii hose set to the PTS ii unit, then connect the hose to a reference pressure gauge known to be accurate (e.g. manometer or calibrated gauge). If required, use the Positive Locking Connector to Luer adapter supplied with your PTS ii unit to connect the end of the PTS ii hose to the reference gauge.

b) Power up the unit by pressing the 'ON/STANDBY' button.

c) Enter the pressure adjustment mode by pressing the pressure adjustment button.

d) Set the pressure set point to 100 mmHg (see section 2.6).

e) Press the inflate button.

f) Allow the pressure to stabilize. The pressure reading on the PTS ii and the reference gauge should be within 5 mmHg of each other, and within 5 mmHg of the pressure set point of 100 mmHg.

g) Repeat steps c) to f) above for 250 mmHg and 475 mmHg.

h) Press and hold the 'DEFLATE' button for 2 seconds to deflate the unit. Disconnect the hose from the PTS ii unit. The pressure reading should decrease to 0 mmHg.

i) If any stabilized pressure reading is off by more than 5 mmHg during the calibration check or the pressure display does not return to zero, the unit must be calibrated. See Section 3.3 below.

2.4.4 ALARM CHECK - "LOW PRESSURE" and "CUFF LEAK"

Connect the hose assembly and a cuff to the PTS ii and press the 'INFLATE' button. The cuff inflates to the default pressure set point of 250 mmHg. Create a leak by partially detaching the hose from the unit while the cuff is inflated. Make the leak large enough that the pressure drops more than 15 mmHg below set point. The pump in the PTS ii unit will start as the unit tries to maintain the set pressure. After the cuff pressure has been more than 15 mmHg below the set point constantly for more than 1 second, confirm that:

a) A "LOW PRESSURE" message alternates with the cuff pressure display (a "CUFF LEAK" message may also appear);

c) The red alarm indicator light is illuminated;

d) The alarm tone sounds constantly.

e) Press the alarm silence key to silence the alarm tone. Confirm that the alarm tone restarts after 30 seconds. Stop the leak and confirm that the displayed pressure returns to the set point and stops flashing, the "LOW PRESSURE" (and "CUFF LEAK" if present) messages disappear, the red alarm indicator light turns off, and the alarm tone stops.

2.5 PRESSURE SET POINT ADJUSTMENT

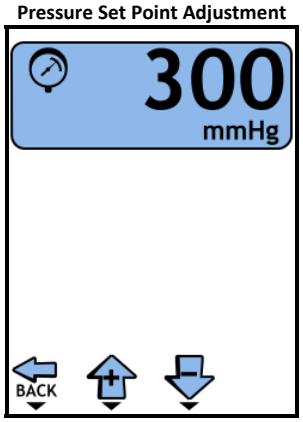
a) At the main screen (Figure 2.5), momentarily press the pressure adjustment button. The PTS ii will display the pressure adjustment screen (Figure 2.6). A pressure gauge icon is displayed and the pressure set point is highlighted to indicate that the set point is being adjusted.

b) Use the increment and decrement buttons to modify the pressure set-point value.

Momentarily pressing the increment button will increase the set point by 5 mmHg. When the button is held the set point will increase by 10 mmHg every second. Momentarily pressing the decrement button will decrease the set point by 5 mmHg. When the button is held the set point will decrease by 10 mmHg every second.

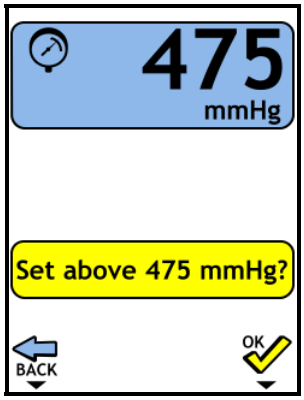
c) Press the back button to return to the main screen. The PTS ii will automatically return to the main screen after 3 seconds if no buttons are pressed.

Figure 2.6
Pressure Set Point Adjustment



d) Note to increase the pressure set point above 475mmHg confirmation is required (Figure 2.7). Momentarily press the OK button to enter extended pressure mode or the press back button to return without entering extended pressure mode. If confirmed pressures above 475 mmHg may be selected. The pressure set-point value and cuff pressure are shown with a yellow background when a pressure set point greater than 475 mmHg has been selected.

Figure 2.7
Extended Pressure Mode



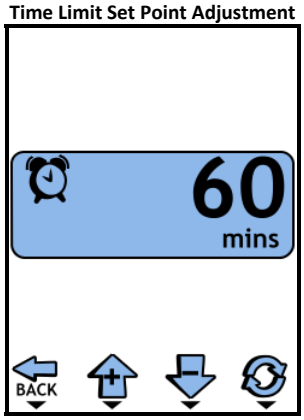
2.6 TIME LIMIT SET POINT ADJUSTMENT

a) At the main screen (Figure 2.5) momentarily press the time limit adjustment button. The PTS ii will display the time adjustment screen (Figure 2.8). An alarm clock icon is displayed and the time limit set point is highlighted to indicate the time limit set-point in being adjusted

b) Use the increment and decrement buttons to modify the pressure set-point value. Momentarily pressing the button labeled with the up arrow will increase the set point by 5 min. When the button is held the set point will increase by 10 min every second. Momentarily pressing the button labeled with the down arrow will decrease the set point by 5 min. When the button is held the set point will decrease by 10 min every second.

c) Press the BACK button to return back to the main screen or wait until the PTS ii automatically returns to the main screen.

Figure 2.8
Time Limit Set Point Adjustment

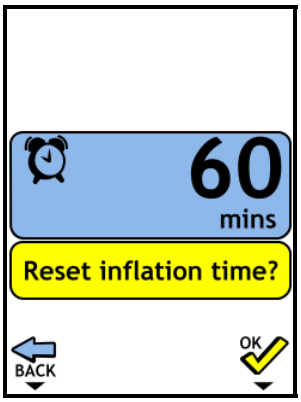


2.7. TOURNIQUET TIME RESET

The elapsed tourniquet time may be reset to zero at any time after the cuff has been inflated.

a) At the time limit set point adjustment screen (Figure 2.7) momentarily press the TIME RESET button. The reset confirmation screen will be shown (Figure 2.9). Press the OK button to reset the time or the BACK button to exit without resetting the time.

Figure 2.9
Time Reset Confirmation



2.8 SETUP / SPECIAL FEATURES

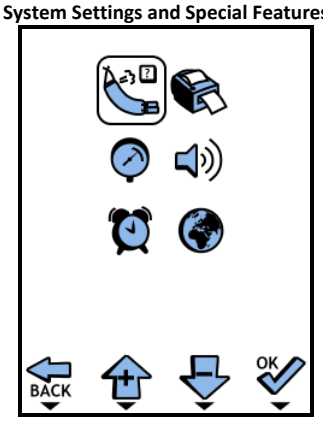
The setup / and special features menu (Figure 2.10) can only be accessed when the cuff is deflated.

a) At the main screen (Figure 2.5) momentarily press the Settings button to select the setup and special features menu. Use the increment and decrement buttons to move the highlighting box up and down to select from the following:

.

	Initiate a test for leakage from the cuff, hose, and connectors
	Set the default pressure set point
	Set the default time limit
	Select the printer label size
	Adjust the audio alarm volume
	Select the system language for messages and printed text

Figure 2.10
System Settings and Special Features



2.9 LEAK TEST

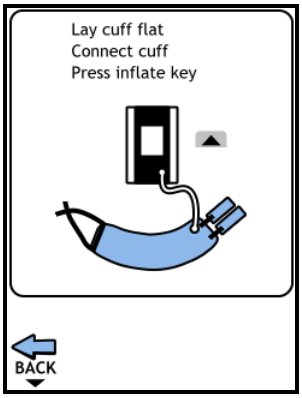
The PTS ii tourniquet system includes an automatic test to check for leakage from an attached cuff, hose and connectors.

a) At the main screen (as show in Figure 2.5) press the settings button to enter the settings menu (as shown in Figure 2.10).

b) To perform a test for leakage from the cuff, hose, and connectors, move the highlighting box to the cuff icon and press the OK button.

c) Connect the cuff as shown in Figure 2.11.

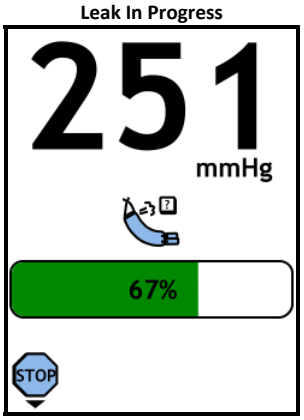
Figure 2.11
Leak Test Instructions



WARNING: Do not start the leakage test (press the INFLATE button) if the cuff is applied to a patient.

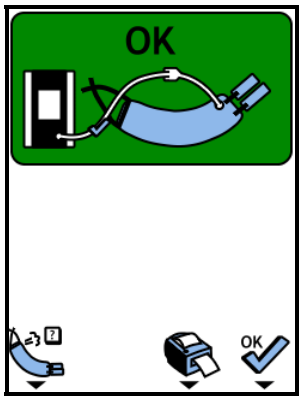
e) Press the INFLATE button to start the test The test can be stopped at any time by pressing the STOP button, this will deflate the cuff (Figure 2.12).

Figure 2.12
Leak In Progress



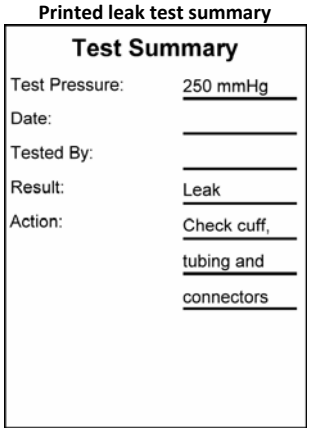
f) The cuff will inflate to approximately 250 mmHg and a 30 second leak test will commence. At the end of the test the cuff will automatically deflate and the test result will display (Figure 2.13). Pressing the CUFF LEAK button will repeat the test.

Figure 2.13
Leak Test Complete



g) Pressing the Print button will print a test summary if the optional printer is connected (Figure 2.14).

Figure 2.14
Printed leak test summary



Test Summary

Test Pressure:	250 mmHg
Date:	
Tested By:	
Result:	Leak
Action:	Check cuff, tubing and connectors

2.10 SET DEFAULT PRESSURE

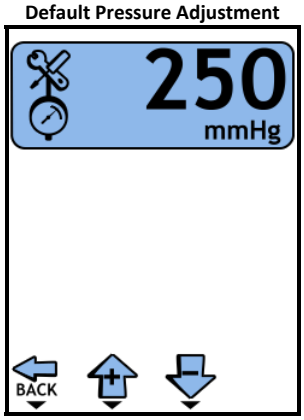
The pressure set point will be set to the default pressure when the system is powered on.

a) At the main screen (Figure 2.5) press the settings button to enter the settings menu (Figure 2.10).

b) To adjust the default pressure set point, move the highlighting box to the pressure gauge icon and press the OK button.

c) Use the increment / decrement buttons to adjust the default pressure set point (Figure 2.15). Use the OK button to accept the new default pressure set point, and return to the settings menu.

Figure 2.15
Default Pressure Adjustment



2.11 SET DEFAULT TIME LIMIT

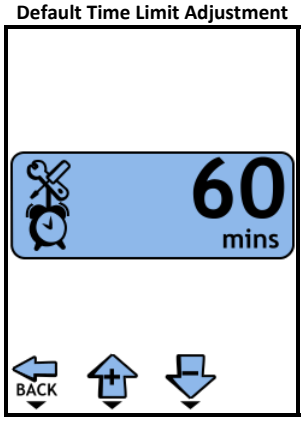
The time limit set point will be set to the default time limit when the system is powered on.

a) At the main screen (as show in Figure 2.5) press the settings button to enter the settings menu (Figure 2.10).

b) To adjust the default time limit set point, move the highlighting box to the clock icon and press the OK button.

c) Use the increment / decrement buttons to adjust the default time limit set point (Figure 2.16). Use the OK button to accept the new time limit set point, and return to the settings menu.

Figure 2.16
Default Time Limit Adjustment



2.12 PRINTER LABEL SIZE

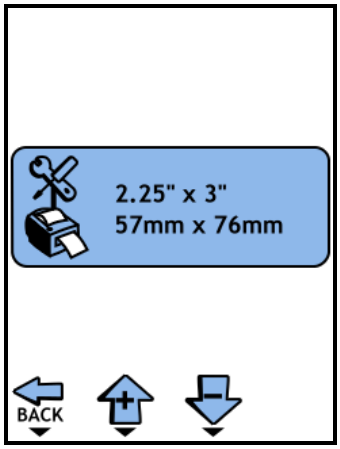
Select the size of the labels used for printing event histories and cuff leak test records.

a) At the main screen (as show in Figure 2.5) press the settings button to enter the settings menu (Figure 2.10).

b) To select a label size, move the highlighting box to the printer icon and press the OK button.

c) Use the increment / decrement buttons to select the printer label size (Figure 2.17). Press the BACK button when done to return to the settings menu.

Figure 2.17
Printer Label Size



2.13 ALARM VOLUME

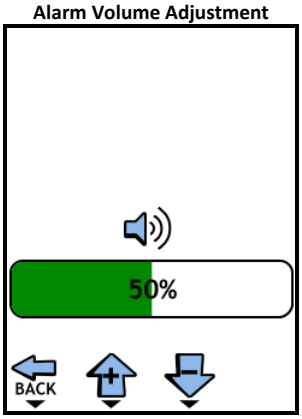
Adjust the volume of the audio tones used to signal alarms.

a) At the main screen (as show in Figure 2.5) press the settings button to enter the settings menu (Figure 2.10).

b) To adjust the alarm volume, move the highlighting box to the speaker icon and press the OK button.

c) Use the increment / decrement buttons to adjust the alarm volume (Figure 2.18),. Press the back button when finished adjusting the volume to return to the settings menu.

Figure 2.18
Alarm Volume Adjustment



2.14 LANGUAGE

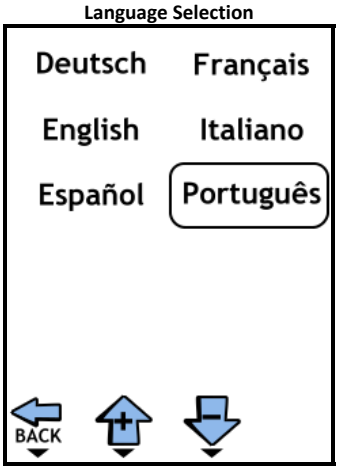
Select the language that will be used for all alarm messages, instructions, and printed text.

a) At the main screen (as show in Figure 2.5) press the settings button to enter the settings menu (as shown in Figure 2.10).

b) To adjust the system language, move the highlighting box to the globe icon and press the OK button.

c) Use the increment / decrement buttons to select the system language (Figure 2.19). Press the BACK button when done to return to the settings menu.

Figure 2.19
Language Selection



2.15 PRINTER

The PTS ii may be used with an optional industry standard thermal label printer (Delfi REF 9-2200-150). The printer is supplied from Delfi with an appropriate interface cable for use with either a single PTS ii system or with two PTS ii systems in a Twin configuration.

Follow the instructions included with the printer to setup and connect the printer to the PTS ii system(s). Note: When using a printer with two PTS ii systems in a Twin configuration both PTS ii systems must be powered on in order to print.

During a surgical procedure the PTS ii maintains a record of tourniquet events such as tourniquet pressure setting, cuff inflation, cuff deflation, alarm events and changes in alarm limits. The tourniquet event record may printed at any time by pressing the print button.

Pressing the print button with the printer disconnected or powered off will produce a “No Printer” alarm. If the printer is connected and unable to print a “Check Printer” alarm will be produced. (See Table 2.1)

The tourniquet event record is remains in the memory of the PTS ii when the PTS ii system is set to Standby. The tourniquet event record is not cleared and new record started until the Inflation button is pressed when the tourniquet time is zero

The PTS ii may be configured to print the record on a single 4”x6” adhesive backed label (Figure 2.20). or on two 2.25”x3” adhesive backed labels (Figure 2.21). Space is provided on the printed labels to record relevant information to the if so desired.

Figure 2.20
Printed Event Record (single label)

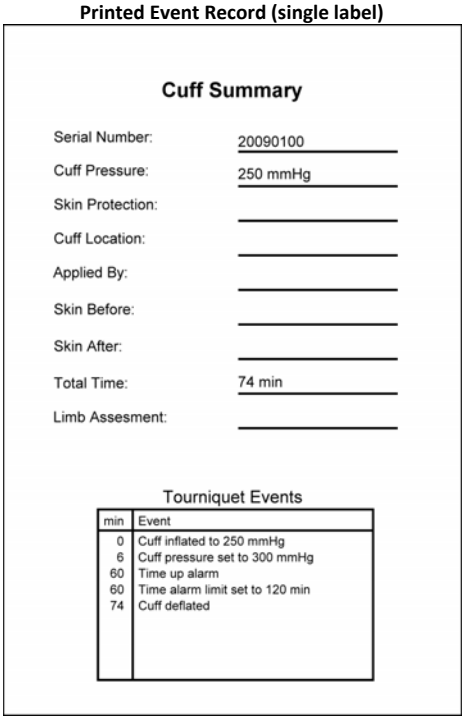
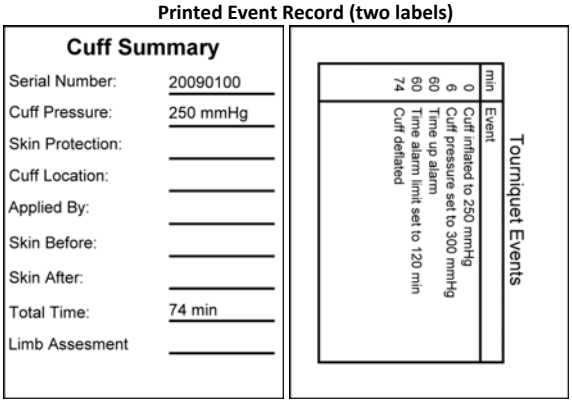


Figure 2.21
Printed Event Record (two labels)



2.16 OPERATION

NOTE: The PTS ii unit should be powered up at least once each day of use to ensure the self-test routine is performed regularly. The PTS ii should be powered off and left plugged in to AC power when not in use.

a) Press the ‘ON/STANDBY’ button to turn the unit on. The unit will execute a self-check diagnostic test as described in Section 2.4.2 of this manual. Successful completion of the self-check indicates that the unit is ready for use.

WARNING: If a connected cuff is pressurized to 50 mmHg or more during power-up, the PTS ii will assume that a surgical procedure is in progress, adopt the pressure sensed in the cuff as the new set point, and will automatically regulate the cuff at this pressure. To alert the operator of this condition, the unit will sound the alarm tone, illuminate the red alarm indicator light, and flash the pressure display. The operator should immediately check the pressure set point and readjust to the proper set point if necessary. The alarm will be cleared as soon as the set point is examined or adjusted via the pressure adjustment mode.

b) Connect the hose assembly and a single port cuff to the unit at the hose connector.

c) Select the appropriate tourniquet pressure and time limit set points for the specific procedure, as specified by the surgeon. The default set points for pressure and time limit are retrieved from the memory during power up and are active until the user adjusts them (see Sections 2.5 and 2.6). These default values can be modified by the user (see Sections 2.10 and 211).

WARNING: In all cases it is essential to check the pressure and time limit set points and confirm that they are the desired values before inflating the cuff.

For each patient, tourniquet pressure required to occlude blood flow to the operative site should be set to the minimum effective pressure. The minimum effective pressure depends on many factors, including the location of the cuff (upper or lower limb), the type of cuff and quality of fit to the limb, whether the limb is normal, hypertrophied, or obese, the patient's preoperative systolic pressure, and the maximum anticipated rise in systolic pressure during the procedure. Refer to the medical literature for current techniques for determining the minimum effective tourniquet pressure for each case.

d) Prepare the patient in accordance with your established procedures and cuff manufacturer's instructions. The precautions of Section 1 and the following are offered as a guide to assist in this process. In most cases a tourniquet cuff should be applied to the widest part of the limb to allow as much tissue as possible to lie between the cuff and any nerves or vascular structures susceptible to damage. The optimum positions are the upper arm and the proximal third of the thigh. In certain cases of fore-foot surgery, the tourniquet cuff can be applied around the calf or to the area proximal to the malleoli. For emergency surgery of the hand, a sufficiently small tourniquet may be selected by the surgeon for fitting around the forearm. Apply a leak-free tourniquet cuff smoothly without wrinkles The hose connections should be placed so that the hose will not be kinked when the limb is positioned for surgery. The viability of the skin and deeper tissues should be established prior to exsanguination of the limb and tourniquet inflation. Exsanguinate the limb by elevating it for a minimum of 2 minutes and wrapping it, distal to proximal, using an Esmarch, Martin, or elastic bandage. The bandage should come up approximately to 1 in. (2.5 cm) from the edge of the tourniquet cuff. The elastic bandage is removed following inflation of the cuff. If regional anesthesia is being used, the anesthetic agent or nerve block is then administered. The surgeon will determine:

- When the tourniquet is to be inflated;
- What pressure is applied;
- How long the tourniquet is applied;
- Whether to allow for intermittent aeration of tissue by deflating the cuff, and the duration of these aeration periods;
- When to deflate and remove the tourniquet.

Appropriate tourniquet time and the need for intermittent deflation of the cuff depend greatly on the patient's anatomy, age, and absence of vascular disease. In many operating rooms, it is customary to prominently note the time of inflation, and to warn the surgeon after a certain time has elapsed. This will allow the surgeon to assess the need for further tourniquet time.

e) Press the INFLATE button when the cuff must be inflated. The unit will pressurize the cuff to the pressure set point and start the tourniquet time clock. If the unit cannot pressurize the cuff to within 15 mmHg of the set point in less than 20 seconds, a leak alarm will be sounded (see Table 2.1 for information about possible alarm conditions). The current pressure in the cuff and the tourniquet time are shown on the LCD display.

f) When the cuff must be deflated, press and hold the DEFLATE button. After holding the button for 2 seconds, the alarm tone will sound briefly, the pressure display will show the falling pressure of the cuff, and the tourniquet time clock will stop and hold the display of the tourniquet time. **Remove the tourniquet cuff and any underlying limb protection material immediately following final cuff deflation**. The time of tourniquet cuff removal should be noted, and the circulation of the limb should be checked. If a minor leak was detected during the surgical procedure a prompt will be displayed stating “TEST FOR LEAKS”. The user should follow the steps listed in section 3.4 to test for leaks.

NOTE: The elapsed tourniquet time can be zeroed after the cuff is deflated by first entering the time adjustment mode by pressing the time limit adjustment soft key at the main screen, followed by pressing the time reset soft key (to reset tourniquet time). Note that the reset feature is only available when elapsed tourniquet time is non-zero.

g) After the cuff has been removed, disconnect the cuff from the PTS ii. During normal use, the PTS ii should not be set to standby if pressure is present in the cuff. Once the cuff has been properly deflated, removed from the patient and disconnected from the PTS ii, the unit can be set to standby.

2.17 ALARM CONDITIONS

There are a number of conditions for which the PTS ii will produce visual and audible alarms. Those conditions, indications and appropriate actions are shown in Table 2.1. The appropriate actions indicated are based on the most probable causes and should only be used as a guide. Other causes of alarm conditions may indicate a need for other actions.
The alarm indicator light is illuminated and an audible alarm tone is produced whenever a alarm condition is detected.

2.20.1 ALARM SILENCE FUNCTION

Most audible alarm tones may be silenced for 30 seconds by momentarily depressing the alarm silence button which is displayed whenever a silencable alarm condition is present. At the end of the silenced period, the alarm tone will restart if the alarm condition has not been corrected. The alarm tone may be silenced for additional 30 second periods as required.

2.20.2 PRESSURE HIGH or LOW ALARMS

A "HIGH PRESSURE" or "LOW PRESSURE" alarm will occur when the pressure in a cuff is more than 15 mmHg from the pressure set point. To minimize nuisance alarms that can be caused by vigorous movement of the patient's limbs, a 1 second delay has been designed into alarm actuation for these conditions.

2.20.3. LEAK ALARMS

It is possible for the system to have a substantial leak that the unit can compensate for by continual pumping. This type of leak could be due to a hole in the cuff or hose assembly, a loose or worn hose connector, or leaks in the pneumatic circuit inside the PTS ii unit. All leaks require immediate attention, because they could progress into a total failure of a cuff to hold pressure at any time. To alert the operator that a substantial leak is present, the "CUFF LEAK" alarm is activated when this type of leak is continuously present for more than 7 seconds, even if the unit is maintaining the cuff pressure within 15 mmHg of the set point. If a "CUFF LEAK" alarm occurs, the cuff, hose assembly, and hose connectors should be checked for leaks. If an external leak cannot be found, test the PTS ii unit per Section 3.4 below.2.8.2.

2.20.4 INTERNAL HARDWARE FAILURES

When "SYSTEM ERROR" and a numeric error code appear in the pressure and time displays during use or power-up, an internal hardware failure has likely occurred and the PTS ii unit is unusable. In this situation, it is likely that the unit has put itself in the 'safe state' mode, in which the pneumatic valve and pump are disabled and the current pressure in the cuff is held (in the absence of leaks). It is also likely that a tone will sound under these conditions. The 'safe state' mode helps prevent unexpected loss of occlusion during a procedure if a sudden failure occurs.

Although it is very unlikely, internal hardware failures may also cause erratic operation and/or unintelligible displays with or without alarms, and may or may not put the PTS ii in the 'safe state' mode.

If either type of error occurs:

a) Set the unit to standby by pressing the 'ON/STANDBY' button. This removes power from the internal instrument circuitry and all instrument functions, causing the cuff to hold pressure (in the absence of leaks).

b) If required, attempt to restart the unit by pressing the 'ON/STANDBY' again to restart the unit.

c) If required to continue the procedure, clamp the hose with a hemostat to maintain cuff pressure, then immediately disconnect the faulty PTS ii unit and connect a replacement unit.

d) If cuff deflation is required, disconnect the cuff from the PTS ii unit.

WARNING: In all cases of internal hardware failure, erratic operation, or unintelligible displays, it is possible that the pressure in the cuff is not accurately displayed on the PTS ii unit and that cuff pressure may be present even when the PTS ii unit appears to be shut down. The user must immediately determine if the cuff is inflated or deflated and continually monitor the cuff to ensure patient safety. If deflation of the cuff is necessary, disconnect the hose from the PTS ii unit or from the cuff and confirm that the cuff deflates completely.

Table 2.1: Alarms and Warnings

Condition		Appropriate action / Remarks
TEST FOR LEAKS The unit has detected leakage from the cuff, hose, or connectors during the time the cuff was inflated. Press the OK button to clear the warning message		This warning is only given when the cuff is deflated. If during the time that a cuff is inflated the PTS ii detects minor leakage from the cuff, hose, or connectors this warning is given. Inspect the cuff, hose, and connectors for damage. Perform a leak test (see 2.X).
CUFF PRESSURE HIGH The unit has detected high pressure in the cuff. High pressure is defined as pressure that is +15mmHg above the pressure set point continuously for more than 1 second	 Alarm message alternates with cuff pressure.	Normally caused by transient conditions such as patient movement, regulator overshoot, or hose occlusion. This condition, for an extended period, would indicate a hardware failure and the PTS ii unit should be replaced. Alarm will stop automatically whenever the unit can regulate the cuff to within 15 mmHg of the pressure set point.
CUFF PRESSURE LOW The unit has detected low pressure in the cuff. Low pressure is defined as pressure that is +15mmHg below the pressure set point continuously for more than 1 second.	 Alarm message alternates with cuff pressure display	This condition is generally caused by a leak in the cuff, hose, connectors or internal system. Connections, hose, and cuff should be checked. Alarm will stop automatically whenever the unit can regulate the cuff to within 15 mmHg of the pressure set point.

CUFF LEAK

The unit has detected a large leak in the cuff, hose or connectors which is defined as the cuff failing to reach the pressure set point in a reasonable time, or the pump running excessively while regulating the pressure and the pressure set point is not being adjusted.

Alarm message alternates with cuff pressure display

Connections, hose, and cuff should be checked and the leak repaired

OR

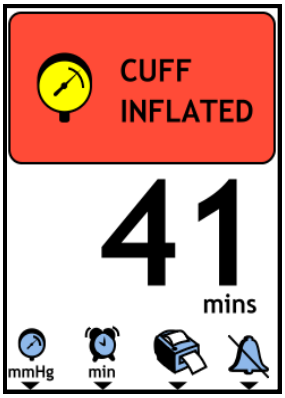
Reduce pressure set point until unit can maintain pressure

OR

Press and hold 'DEFLATE' for 2 seconds to deflate the cuff

CUFF PRESURIZED DURING POWER UP

The unit has detected an approximate pressure of 50mmHg or more in the cuff when the unit was powered up. The unit assumes a procedure is in progress, changes the pressure set point to the detected pressure, immediately regulates the cuff to this pressure, and activates alarm to alert the user of the condition.



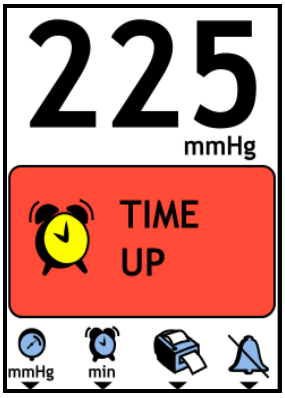
Alarm message alternates with cuff pressure display

The system assumes that a procedure is in progress and adopts the sensed pressure as the new set point. The operator should immediately check the set value to determine if it needs reset

Press the pressure adjustment button and verify the cuff pressure set point

TOURNIQUET TIME LIMIT EXCEEDED

The unit's elapsed timer, which advances when the cuff is inflated, has reached the time limit set point and caused the time alarm to activate.



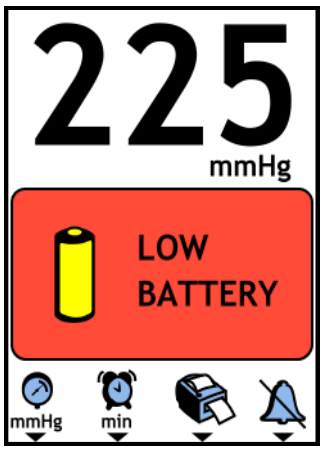
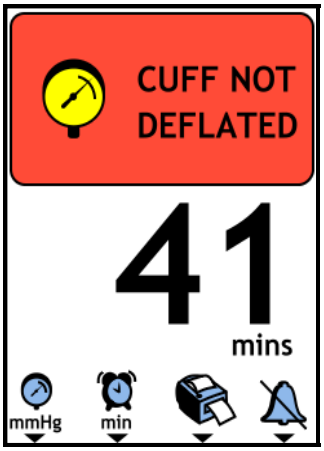
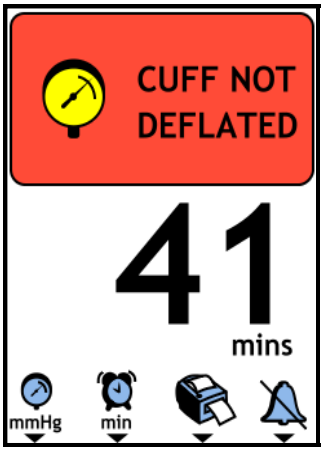
Alarm message alternates with elapsed time display

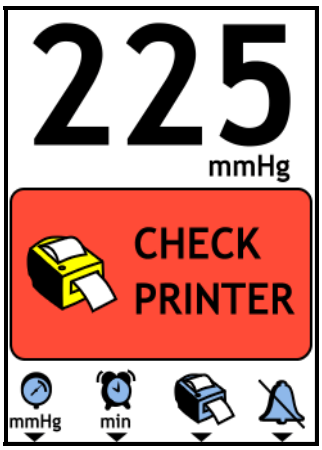
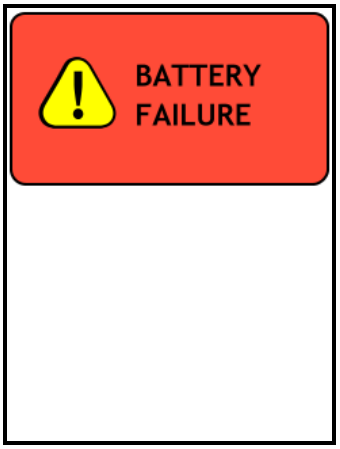
The surgeon should be warned of the time up condition. Only on the direction of the surgeon, should the time limit be set to new value.

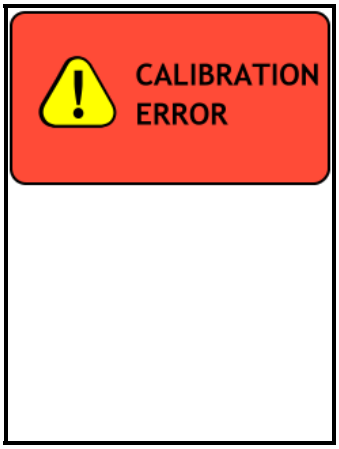
Press the time limit adjustment button and increase the time limit.

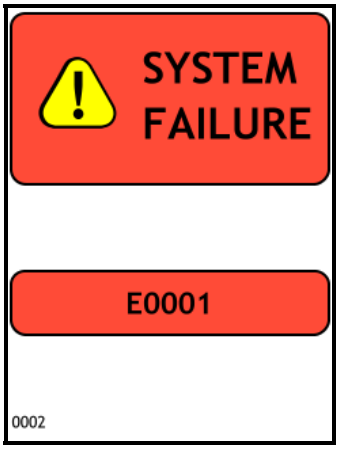
OR

Press and hold 'DEFLATE' for 2 seconds to deflate the cuff

LOW BATTERY The battery voltage has dropped to a level indicating that the unit should be plugged into AC power for continued use, and to charge the battery.	 Alarm message alternates with elapsed time display	Plug unit in. If the unit is not plugged in, a battery failure condition will occur and the unit will shut down in a fail safe mode closing all valves. **While running with a Low Battery Voltage Alarm Condition other alarm conditions can not be guaranteed.** OR Press 'ON/STANDBY' to shut unit down.
CUFF NOT FULLY DEFLATED The unit has detected pressure in the cuff greater than 15mmHg, 30 seconds after the cuff has been deflated.	 Alarm message alternates with cuff pressure display	Disconnect hose to cuff to exhaust pressure
ATTEMPT TO POWER OFF UNIT WITH CUFF PRESSURIZED The unit has detected that the operator has attempted to set the unit to standby with pressure remaining in the cuff.	 Alarm message alternates with cuff pressure display	Press and hold 'DEFLATE' for 2 seconds to deflate the cuff, then press 'ON/STANDBY' to shut the unit down.

CHECK PRINTER The unit has detected that the printer is not ready to print.	 Alarm message alternates with elapsed time display	Check that the printer is not out of labels; the labels are correctly installed; and the printer door is fully closed.
NO PRINTER The unit can not communicate with the optional printer.	 Alarm message alternates with elapsed time display	The unit was unable to communicate with the optional printer. Check to make sure the printer is correctly connected to the PTS ii, and powered on.
BATTERY FAIL The battery voltage has dropped below the threshold of safe operation and has shut down in a safe state* OR The battery has been removed/disconnected.		Press 'ON/STANDBY' to shut unit down. When cuff deflation is required, disconnect hose to cuff. Ensure that the battery is connected properly. Plug in AC power to attempt to recharge the battery. Service or replace the battery pack (see Section 3.5 below).

CALIBRATION FAILURE The unit has detected that the calibration in the pressure transducer is invalid. The unit has shut down in a safe state*. (See also Calibration Procedure, Section 3.3)		Disconnect the hose and press 'ON/STANDBY' twice to shut unit down and restart OR Calibrate the unit per Section 3.3

INTERNAL ELECTRONIC FAILURE The unit has detected an internal error and has shut down in a safe state		Press 'ON/STANDBY' twice to shut unit down and restart. When cuff deflation is required, disconnect hose to cuff
*** In the 'safe state' mode, the current pressure in the cuff is held (in the absence of leaks). The 'safe state' mode helps prevent unexpected loss of occlusion during a procedure if a sudden failure occurs. See Section 2.8.2 for more detail.**		

MAINTENANCE INSTRUCTIONS

SECTION 3.0

DELFI PTS ii TOURNIQUET SYSTEM

3.1 GENERAL MAINTENANCE INFORMATION

While the PTS ii has been designed and manufactured to high industry standards, it is recommended that periodic inspection, testing, and calibration ('maintenance') be performed as described in this section to ensure continual safe and effective operation. This section also serves as a guide to troubleshooting and expediting unscheduled maintenance. The maintenance intervals listed below are provided as a guideline; refer also to the policies in your practice setting for general tourniquet maintenance procedures and intervals.

CAUTION: Do not attempt to disassemble or open the enclosure of your PTS ii unit. The PTS ii is not designed to be disassembled and serviced by anyone other than Delfi staff. Disassembly and attempted service by anyone other than Delfi staff poses a risk of electric shock, damage to the unit, and injury to the patient and will void all warranties. Internal parts in the PTS ii can only be serviced at the factory by Delfi staff. Please contact Delfi if you have problems with your PTS ii unit that cannot be resolved by following the maintenance and troubleshooting procedures described below.

3.2 PERIODIC MAINTENANCE

3.2.1 CLEANING

The exterior of the unit may be cleaned as often as required with a cloth that has been dampened (not dripping) with a mild detergent. The exterior of the cuff hose may be cleaned using a mild detergent solution or alcohol. Tourniquet cuffs should be cleaned in accordance with the manufacturer's instructions.

CAUTION: Do not attempt to clean or flush out the interior of the hose assembly. Do not allow fluids or debris to enter the hose connectors on the PTS ii unit or the hose assembly.

CAUTION: Avoid exposing the AC power supply to liquids. Do not immerse in fluid. Do not allow the AC power supply to lie on the floor where pooling of liquids may occur. Clean by damp cloth (alcohol or mild detergent wipe) only. The AC power supply is resistant to occasional splashing or dripping of fluids, but is not fluid-tight. If immersed in or exposed to excessive amounts of liquids, the AC power supply may fail and may pose an electrical shock hazard.

3.2.2 INSPECTION

The unit should be externally inspected as follows at least once every three months:

- Obvious external damage.
- Missing or illegible labels and warnings.
- Kinks or damage in the power cord.
- Secure connection and locking of the power cord plug to the receptacle on the PTS ii unit.
- Secure connection and locking of the hose connectors on the PTS ii unit to the hose assembly.
- Kinks or damage in the hose assembly.

3.2.3 FUNCTIONAL AND CALIBRATION CHECKS

The functional and calibration checks described in Section 2.5 should be performed at least once every three months.

3.3 CALIBRATION

Calibration should be performed every six months, or after any unscheduled maintenance.

Calibration of the PTS ii allows the output signal from the pressure transducers to be compared against a calibrated pressure source. The difference between the known pressure and the pressure measured by the transducers is recorded at each of four set points, and these four calibration factors are used to correct the signal from the pressure transducers during normal operation. The calibration factors are stored in memory.

EQUIPMENT REQUIRED:

- Calibrated 0 to 650 mmHg pressure gauge.
- Adjustable 0 to 650 mmHg pressure source.
- Suitable pneumatic hoses and connectors.

CAUTION: The following steps must be taken in the exact order to calibrate the unit. Failure to do so may result in incorrect pressure readings while the unit is in operation.

a) To enter the calibration mode, press and hold the 'INFLATE' and 'DEFLATE' buttons simultaneously, then press 'ON/STANDBY' to switch the unit on. When the unit finishes its start-up sequence the unit will enter the calibration mode and display "0 mmHg" under the current pressure display. This is to indicate to the user that the unit is now ready to calibrate 0 mmHg.

b) With the hose connector on the PTS ii unit open to atmosphere, press the OK button to indicate zero reference pressure is applied. The unit will adjust the transducer output corresponding to zero pressure. The unit will then sound a tone to indicate that the reference pressure was taken.

c) Once the zero point is calibrated, press the increment / decrement buttons to advance the unit to the next pressure level. The display will now show "100 mmHg". Connect the PTS ii to the reference pressure source and gauge. Apply a calibrated reference pressure of 100 +/- 1 mmHg to the cuff port. Once the pressure has stabilized, press the OK button to indicate the reference pressure is applied. The unit calibrates the 100mmHg point and sounds a tone when successfully completed. If the reference pressure is more than 15 mmHg different from the sensed pressure, the unit will show "CALIBRATION ERROR" in the pressure display and will not accept the pressure applied. If this happens, try to adjust it to a correct pressure.

d) Repeat the preceding step for reference pressures of 300 +/- 1 mmHg and 600 +/- 1 mmHg. The unit will not allow calibration points to be missed.

e) Remove the reference pressure source and press the stop soft key. Power off the unit by pressing the 'ON/STANDBY' button.

3.4 LEAK TESTING

Leak testing should be performed at least once every six months, or if leak alarms occur without an obvious cuff or hose leak. The PTS ii is capable of maintaining cuff

pressure even with a substantial leak in the system; however any leak may become worse and lead to loss of occlusion during a procedure, so it is important to find and correct leaks as soon as possible.

a) Connect a leak-free Delfi Contour Lower Leg cuff, Contour Arm cuff, or a similar sized cuff to the PTS ii using the hose assembly.

b) Enter leak test mode by pressing the settings soft key and then pressing the OK button while the cuff test icon is selected.

c) Press the inflate key and wait for a report from the PTS ii.

d) If "LEAK" or "LARGE LEAK" are displayed there is a significant leak in either in the test cuff and hose or in the PTS ii internal pneumatics. Repeat the test with a variety of different cuffs and hose assemblies. If the unit continues to fail, the leak is internal and the PTS ii unit must be serviced by Delfi.

3.5 BATTERY TESTING AND REPLACEMENT

CAUTION: Risk of electric shock. Set the PTS ii unit to standby and disconnect AC power before opening the battery compartment.

NOTE: It is recommended that the battery in the PTS ii be tested as described below every 3 months and replaced annually. Even when the PTS ii is used on AC power, the battery pack must be in good condition to provide backup power in the event of the AC power being disconnected.

A new battery pack is designed to run the PTS ii without AC power for about 10 hours of typical use on a full charge, however this charge life will vary greatly depending on the conditions of use. The life and performance of the battery pack also depends on the conditions of use and storage. Battery replacement will need to be more frequent with continued cycles of deep discharge and/or storage at high temperatures. Infrequent short-term use of the battery and storage at room temperature or lower will result in maximum life.

The PTS ii features automatic battery charging and monitoring functions and attempts to charge the battery whenever the unit is connected to AC power, both in on and standby modes. No maintenance is required of the battery charging circuit. To check the charge level in the battery, the PTS ii must be on with no AC power connected. When on under battery power, the battery indicator symbol appears in the message display (see Figure 2.1 When the colored bar completely fills the battery icon, the battery has a full charge. Reducing length of the bar and the change in color from green to red progressively indicate decreasing battery capacity and the need for recharging.

3.5.1 BATTERY TESTING

To determine if the battery pack needs replacement, charge it for at least 10 hours and then test as follows:

a) Remove the AC power supply and power up the PTS ii unit. The battery indicator symbol should be visible in the LCD display and the battery symbol should be completely filled.

b) Connect the PTS ii. to a tourniquet cuff and inflate to 350 mmHg.

c) If only one red segment shows after 1 hour, replace the battery pack.

The battery pack must also be replaced if a "BATTERY FAILURE" alarm condition occurs (see Table 2.1) that cannot be corrected by plugging the PTS ii unit into AC power or by confirming that the battery pack is securely connected. You may also wish to replace the battery pack if you regularly use your PTS ii on battery power and have "LOW BATTERY" alarm conditions occurring soon after a full charge.

3.5.2 BATTERY PACK REPLACEMENT

WARNING: Use only Delfi REF 7-2200-007 NiMh battery packs. Do not use any other batteries. Use of improper batteries may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the PTS ii unit.

WARNING: When a new battery pack is installed, the PTS ii must be plugged in to AC power for at least 10 hours to fully charge the new battery before use.

a) Remove the single battery cover screw from the back of the PTS ii unit (directly above the label) and remove the battery cover.

b) Remove the old battery pack and unplug it by pulling the battery wires straight up from the battery compartment. This will disconnect the battery connector from the two-pin plug inside the PTS ii unit. **Recycle or dispose of the old battery pack in accordance with local regulations and procedures.**

c) Install the new battery pack supplied by Delfi by aligning the keyed plug and pushing the connector onto the four-pin plug inside the PTS ii unit. Push the connector all the way down until it stops. The top of the connector will be about flush with the battery compartment surface. The connector cannot be installed the wrong way; if it will not slide easily all the way down, rotate it one-half turn and try again.

3.6 INTERNAL HARDWARE SERVICING

The PTS ii is designed with self-test and self-monitoring features to warn of failures (see Table 2.1). Although it is very unlikely, modes of failure may also occur that cause erratic operation and/or illegible displays and may or may not trigger alarms. If the maintenance, calibration, and troubleshooting procedures described above do not restore normal operation, contact Delfi for service advice.

CAUTION: Do not attempt to disassemble or open the enclosure of your PTS ii unit. The PTS ii is not designed to be disassembled and serviced by anyone other than Delfi staff. Disassembly and attempted service by anyone other than Delfi staff poses a risk of electric shock, damage to the unit, and injury to the patient and will void all warranties. Internal parts in the PTS ii can only be serviced at the factory by Delfi staff. Please contact Delfi if you have problems with your PTS ii unit that cannot be resolved by following the maintenance and troubleshooting procedures described above

3.7 TROUBLESHOOTING GUIDE

Table 3.1 lists a number of possible malfunctions and their most likely causes. While it is not possible to list every conceivable malfunction and possible causes, the table will help the user solve the most common problems.

Table 3.1: Troubleshooting

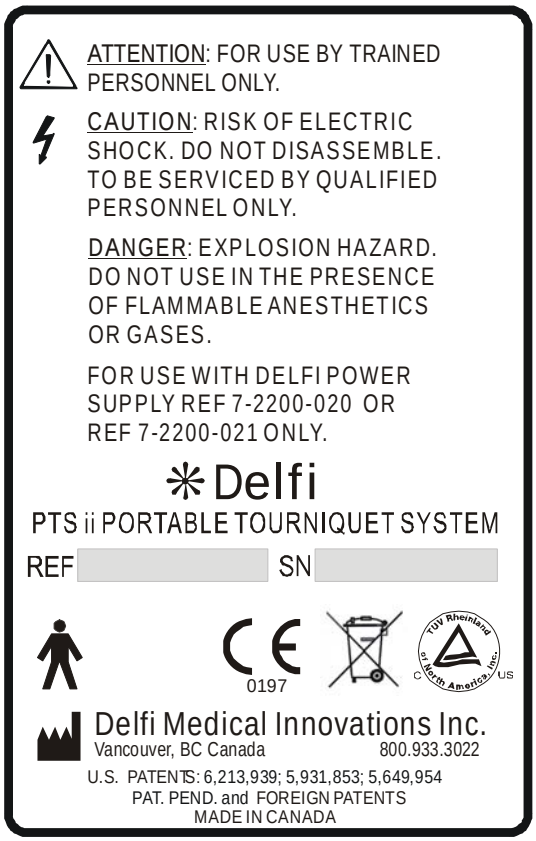
MALFUNCTION	POSSIBLE CAUSES	CORRECTIVE ACTIONS
Unit does not turn on (with no AC power connected).	**Battery pack not charged.**	**Plug in to AC power and allow battery to charge. Attempt to turn unit on with AC power (see "BATTERY FAILURE" alarm below).**
	Battery pack disconnected.	**Remove battery cover and ensure battery pack is securely plugged in.**
Unit does not turn on (with AC power connected).	**Internal hardware failure. Defective AC adapter/cord assembly.**	**Contact Delfi.**
Cuff does not inflate.	**Internal hardware failure.**	**Contact Delfi.**
Cuff does not deflate.	**'DEFLATE' button not held for 2 seconds.**	**Press and hold the 'DEFLATE' button for at least 2 seconds.**
	Hose kinked or blocked.	**Unkink hose or disconnect cuff from hose. Ensure complete cuff deflation to clear "CUFF NOT DEFLATED" alarms.**
	Internal hardware failure	**Contact Delfi.**

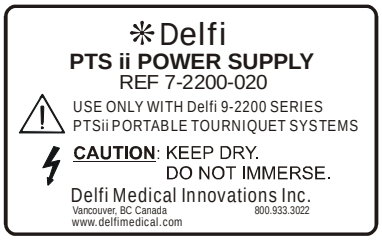
Green AC indicator light does not illuminate when unit is plugged in to AC power.	**AC power supply assembly not plugged in to suitable wall outlet.** **AC power supply assembly not plugged in to PTS ii unit.** **Incorrect AC power supply assembly.** **AC power supply not working** **AC indicator light not working.**	**Ensure wall socket is working, of the correct voltage, and that the plug is all the way in.** **Ensure connector is fully engaged.** **Ensure AC power adapter is the one supplied with the PTS ii unit.** **Contact Delfi.** **Contact Delfi.**
Red Alarm indicator light does not illuminate during alarm conditions.	**Alarm indicator light not working.**	**Confirm that alarm indicator light illuminates during self-check upon power-up. Contact Delfi.**
No cuff pressure and/or tourniquet time reading.	**Faulty pressure/time display.** **Internal hardware failure.**	**Confirm that all segments of the display illuminate during self-check upon power-up.** **Contact Delfi.**
Pump runs continuously.	**External leak (cuff or hose).** **Internal leak.** **Internal hardware failure.**	**Correct leak to clear leak alarm.** **Test for leaks (see Section 3.4 above).** **Disconnect PTS ii from cuff to deflate cuff if required. Contact Delfi.**
BATTERY FAILURE alarm.	**Fully discharged battery** **Battery pack disconnected.** **Faulty or dead battery pack.**	**Connect to AC power and allow battery to recharge for 10 hours.** **Remove battery cover and ensure battery pack is securely plugged in.** **Replace battery pack (see Section 3.5 above).**
Battery does not charge when unit is plugged in to AC power.	**Faulty or dead battery pack.**	**Replace battery pack (see Section 3.5 above).**
Unit does not turn off (cannot be set to standby)	**Pressure in cuff** **Internal hardware failure**	**Deflate cuff and ensure it deflates fully (disconnect hose if required) to clear "CUFF NOT DEFLATED" alarm.** **Contact Delfi. Unit can be powered off by unplugging the AC power and removing the battery pack (see Section 3.5).**

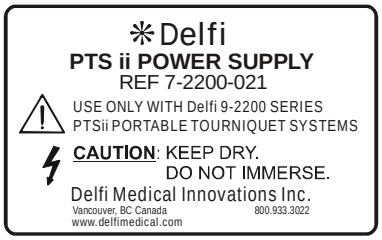
WARNINGS, CAUTIONS, LABELS, and SYMBOL DEFINITIONS

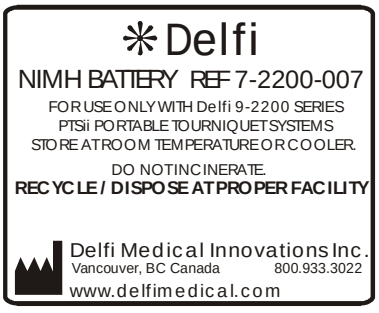
	Type B Medical Equipment		Earth ground
	Refer to operator and maintenance manual	~	Alternating Current
	Electrical hazard: Dangerous voltage	▬	Direct current
CE	Conformity marking of the Council of the European Community		
	cTUVus: Medical Equipment with respect to electrical shock, fire and mechanical hazards and electromagnetic compatibility only. In accordance with CAN/CSA – C22.2 No.601.1-M90, UL 60601-1, and IEC 60601-1-4 and IEC 60601-1-2		
EC REP	Authorized representative in the European Community		
	Manufacturer name and address		
	This symbol means that electrical and electronic equipment, at their end-of life, should be disposed of separately. Please, dispose of this equipment at your local community waste collection/ recycling centre.		

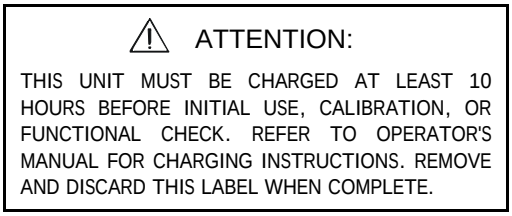
Figure 3.1: Labels











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